Group III – Claims 2-12, drawn to a device wherein the active substance is selected from the genus of oligonucleotides or polynucleotides.

Group IV – Claims 2-10 and 12, drawn to a device wherein the vaccine is selected from the genus of bacterial or bacterial toxoid vaccines.

Group V - Claims 2-10 and 12, drawn to a device wherein the vaccine is selected from the genus of viral vaccines.

Group VI - Claims 2-10 and 12, drawn to a device wherein the vaccine is selected from the genus of oligonucleotide or polynucleotide vaccines.

Group VII - Claims 2-10 and 12, drawn to a device wherein the vaccine is selected from the genus of genetically engineered antigens.

The Examiner explains in the Office action that claim 1 links inventions II – VII and that the restriction requirement between the linked inventions is subject to the non-allowance of the linking claim 1. Therefore, upon the indication of allowability of the linking claim, the restriction requirement as to the linked inventions shall be withdrawn and any claims depending from or otherwise requiring all the limitations of the allowable linking claim will be rejoined and fully examined for patentability.

The Examiner further states that the inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features since the common technical feature among the inventions is the device for transdermal administration of active substances, which lacks an inventive step as evidenced by U.S. Patent No. 6,656,147 (Gertsek, et al.) in view of U.S. Publication No. 2002/0016562

(Cormier, et al.). Specifically, the Examiner argues on in the Office action that Gertsek, et al. disclose a device for transdermal administration of active substances comprising a plurality of microneedles, and that the device comprises a back layer and a reservoir connected to the back layer. Thus, the Examiner concludes that the reference teaches each element of claim 1 except for the needles having undercuts or barbs.

The Examiner refers to Cormier, et al. for teaching a transdermal delivery device comprising barbed microblades that function to adhere the device to the skin. The Examiner concludes that since essentially identical transdermal delivery devices were known in the art at the time of invention, one of ordinary skill in the art would readily have envisioned constructing the device of Gertsek, et al. with undercuts or barbs to increase adherence of the device to the skin as taught by Cormier, et al. Therefore, the Examiner argues that the claimed device lacks an inventive step and the Groups cannot share a special technical feature since the device is not a special technical feature as defined under PCT Rule 13.2.

The Applicant hereby elects the claims of Group III (which reads on claims 2-12, drawn to a device wherein the active substance is selected from the genus of oligonucleotides or polynucleotides, and which includes claim 1) for further prosecution on the merits thereof. However, the Applicant respectfully submits the instant claim election, with traverse, as discussed below.

The Applicant submits that the present invention provides an improved device for transdermal delivery of active substances wherein the device is fixed on the patient's skin solely by the protrusions providing enhanced skin penetration of the active substance and

wherein the device provides enhanced permeability of the active substance. With respect to this particular underlying inventive concept, the specific kind of active substance to be delivered is not of significant importance. Therefore, the present invention is based on a single invention.

Regarding the Examiner's discussion of Gertsek, et al. in view of Cormier, et al., the Applicant submits that Gertsek, et al. teach a device for transdermal delivery of active substances wherein the device comprises a plurality of needles for penetrating the stratum corneum and a reservoir with a liquid formulation of active substance contained in a bladder. The device additionally contains a pressure sensitive adhesive for attaching the housing to the skin (column 5, lines 6-12). Therefore, Gertsek, et al. fail to teach either needles having undercuts, or the attachment of a device to the skin solely by the needles.

Cormier, et al. disclose a device for piercing the stratum corneum. The piercing device comprises a metal sheet having blades (emphasis added) made by punching or etching. The blades have been bent out of the plane of the metal sheet. Due to this production process, the device has at least one opening in the metal sheet through which the active substance has to be applied, while the major part of the skin contacting surface is blocked by the metal sheet. Therefore, the device of Cormier, et al. clearly has a limited cabability to apply active substances to the skin.

The Applicant notes that although some of the blades of Cormier, et al. may comprise a barb to fix the device on the skin, these protrusions in blade form are clearly not suited to sufficiently anchor the device to the skin (as compared to the present invention, e.g., paragraph [0018] of the present description). This becomes even clearer

when taking into account that the piercing device represents only a small area of the whole application device as shown in Figures 1, 22 and 25 of Cormier, et al. The Applicant thus submits that it is clear that the barbed blades are not intended whatsoever to fix the application device to the skin solely by this manner, and that additional apparatus or mechanism for attachment (such as adhesives) would be required. Therefore, the primary function of the blades of the Cormier, et al. device was not for the attachment of the device to the skin, but rather to pierce the stratum corneum to enhance the application of substances or drawing of samples (in accordance with column 5, lines 38-40 of Cormier, et al., where it states that "[t]his blade geometry provides maximum drug percolation area with a minimum blade penetration area, and hence less tissue damage."). Thus, due to the special form of the blades of Cormier, et al., less tissue would be damaged than by the use of standard round elements such as needles and tubes (column 5, lines 45-50).

In contrast to the above, the microprotrusions in the present invention not only are needle-shaped but additionally show undercuts to anchor the protrusions into the skin. Therefore, according to Cormier, et al., one skilled in the art would expect <u>even more</u> tissue damage when using needle-shaped protrusions with undercuts. In this regard, it is respectfully submitted that the disclose of Cormier, et al. teaches away from the presently claimed invention and thus one skilled in the art would not have had any motivation to combine the teachings thereof with those of Gertsek, et al. with the expectation of arriving at the presently claimed invention.

Moreover, the device as defined in present claim 1 includes another certain

advantage over the prior art. In particular, since it is possible to attach the device without any adhesive, the devices are especially suited for patients having allergic reactions to components of established adhesives which are commonly used for transdermal devices and patches.

It has further been found in the presently claimed device, in contrast to the teachings of the prior art (in particular those of Cormier, et al.) that the transdermal devices can be solely attached to the skin by microprotrusions having undercuts and that the microprotrusions provide sufficient holding ability without any further apparatus or mechanism of attachment. As discussed at length above, the present device as set forth in claim 1 would clearly not have been rendered obvious by Gertsek, et al. in view of Cormier, et al. and is thus clearly based on an inventive step.

In summary, the presently claimed invention is novel and inventive. The Applicant thus respectfully requests that the Examiner's restriction requirement be reconsidered and withdrawn.

The Examiner is invited to call the undersigned if there are any remaining issues to be discussed which could expedite the prosecution of the present application.

Respectfully submitted,

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